UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FWK HOLDINGS LLC, *on behalf of itself and all others similarly situated*	*	
Plaintiffs,	*	
v.	*	Civil Action No. 16-cv-12653-ADB
SHIRE PLC, SHIRE, LLC, SHIRE U.S., INC., ACTAVIS ELIZABETH LLC, ACTAVIS HOLDCO US, INC., and ACTAVIS LLC,	*	
Defendants.	*	

MEMORANDUM AND ORDER ON MOTIONS TO DISMISS

BURROUGHS, D.J.,

Plaintiff FWK Holdings LLC brings this putative class action on behalf of direct purchaser plaintiffs ("DPPs")[1] of the pharmaceutical drug Intuniv, alleging an illegal reverse payment settlement agreement between Defendants Shire PLC, Shire, LLC, and Shire U.S., Inc. ("Shire"), and Actavis Elizabeth LLC, Actavis Holdco US, Inc., and Actavis LLC ("Actavis") (collectively, "Defendants"). Currently pending before this Court are Shire's and Actavis's separate motions to dismiss for failure to state a claim. [ECF Nos. 49, 52]. For the reasons stated below, the motions are DENIED.

[1] Plaintiff defines the class as: "All persons or entities in the United States and its territories, or subsets thereof, that purchased Intuniv and/or generic Intuniv in any form directly from Shire or Actavis, including any predecessor or successor of Shire or Actavis, from October 5, 2012 until the effects of the defendants' conduct ceased," except "Shire, Actavis, and any of their officers, directors, management, employees, subsidiaries, and affiliates." CAC ¶¶ 197, 198.

I. PROCEDURAL BACKGROUND

On December 30, 2016, the DPPs filed the original complaint. [ECF No. 1]. On February 2, 2017, the case was reassigned to this session, given its relation to Picone et al. v. Shire U.S., Inc. et al., No. 16-cv-12396, in which plaintiffs are indirect purchasers of Intuniv. On March 1, 2017, the Court granted a joint motion to consolidate this case with Rochester Drug Co-operative, Inc. v. Shire LLC, et al., No. 17-cv-10050. [ECF No. 19]. On March 13, 2017, Plaintiff filed a consolidated amended class action complaint under seal ("CAC"). [ECF No. 32]. The next day, the plaintiff in Rochester Drug voluntarily dismissed its case without prejudice. [No. 17-cv-10050, ECF No. 27]. On April 10, 2017, Defendants filed separate motions to dismiss [ECF Nos. 49 & 52], which the DPPs opposed [ECF No. 63]. Defendants also filed replies to the opposition. [ECF Nos. 67, 68]. On July 20, 2017, the Court held a hearing on the motions to dismiss in both the instant action and the related action, No. 16-cv-12396. [ECF No. 78].

II. ALLEGATIONS IN THE COMPLAINT

A. Regulatory Background

Under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq. ("FDCA"), a drug manufacturer must obtain approval from the Food and Drug Administration ("FDA") to sell a new drug by filing a New Drug Application ("NDA"). 21 U.S.C. § 355(b)(1). The NDA discloses any patents that claim the new drug, and, if approved, the manufacturer must list these patents in the FDA publication known as the "Orange Book." See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 542 (1st Cir. 2016). The FDA does not independently assess the validity and enforceability of patents listed in the Orange Book.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585, commonly known as the Hatch–Waxman Act, a generic manufacturer may file an Abbreviated New Drug Application ("ANDA") to seek approval of a proposed generic version of a brand drug. See 21 U.S.C. § 355(j). Obtaining approval for an ANDA is simpler than obtaining approval for an NDA. In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 543. As part of the ANDA, a generic manufacturer must certify, in one of four ways provided by statute, that the generic does not infringe any patents listed in the Orange Book. See 21 U.S.C. § 355(j)(2)(A)(vii). In a "Paragraph IV" certification, the ANDA filer certifies that the patent claiming the brand drug "is invalid or will not be infringed by the manufacture, use, or sale of the" proposed generic. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This constitutes a constructive act of infringement granting the brand company standing to sue the ANDA filer. 35 U.S.C. § 271(e)(2)(A). If a brand company files a patent infringement suit against the ANDA filer within 45 days of receiving notice of the certification, the ANDA is automatically stayed for 30 months or pending an outcome in the lawsuit favorable to the ANDA filer. 21 U.S.C. § 355(j)(5)(B)(iii). The first generic company to file an ANDA before the expiration of all the Orange Book-listed patents, if ultimately successful, is granted a 180-day period of exclusivity from any other generic manufacturers. Id. at § 355(j)(5)(B)(iv). A brand manufacturer may still introduce its own authorized generic ("AG")[2] during this time period. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 543 (citing Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54−55 (D.C. Cir. 2005)).

[2] "An authorized generic is a generic drug sold by the company who markets the brand name drug (or a third party licensee). Authorized generics, like other generics, are sold at a reduced price compared to the brand name drug." Sanofi-Aventis v. Apotex Inc., 659 F.3d 1171, 1174–1175 (Fed. Cir. 2011) (citation omitted).

B. Intuniv

In September 2009, the FDA approved Shire's NDA application to market extended-release guanfacine hydrochloride tablets (in one, two, three, and four mg dosages) as Intuniv for the treatment of attention deficit hyperactivity disorder in children and adolescents. CAC ¶ 98. Shire listed three patents in the Orange Book as covering Intuniv: U.S. Patents Nos. 5,854,290 (the '290 patent), 6,287,599 (the '599 patent), and 6,811,794 (the '794 patent) (collectively, "the Intuniv Patents").[3] Id. ¶ 99. Shire's patents do not directly claim Intuniv's active ingredient, guanfacine hydrochloride, but instead consist of one method-of-use patent and two patents covering the coating that enables a gradual release mechanism. Id. ¶ 102. Shire manufactured, distributed, and sold brand Intuniv during the class period. FWK Holdings LLC (as the assignee of the claims of Frank W. Kerr Co.) and the DPPs purchased brand Intuniv directly from Shire and/or generic Intuniv directly from Actavis during the class period. Id. ¶¶ 20, 195. Plaintiff claims that Shire knew that the Intuniv Patents were weak, and nonetheless listed them in the Orange Book to deter generics. Id. ¶ 103.

C. Generic Manufacturers Challenge the Intuniv Patents

On December 29, 2009, Actavis filed the first ANDA with a Paragraph IV certification to market a generic Intuniv, arguing that all three of Shire's Intuniv patents were invalid or not infringed. Id. ¶ 107. Following Actavis's ANDA, other generic manufacturers that are not parties to this suit filed ANDAs to market generic Intuniv: Teva Pharmaceuticals USA, Inc. ("Teva") on

[3] The '599 Patent is set to expire December 20, 2020; the '794 Patent is set to expire July 4, 2022; and the '290 Patent was dedicated to the public in the course of patent litigation, but otherwise would have been set expire on September 21, 2015. CAC ¶ 99−101.

January 25, 2010; Anchen Pharmaceuticals, Inc. ("Anchen")[4] on January 28, 2010; Mylan Pharmaceuticals, Inc. ("Mylan") on November 30, 2010; Sandoz, Inc. ("Sandoz") on December 28, 2010; Impax; and Watson. Id. ¶¶ 9, 108. Teva, Actavis, and Anchen sent Paragraph IV notice letters to Shire in March and April 2010. Id. ¶ 109.

Shire then initiated patent infringement litigation against the generic manufacturers in the District of Delaware, which triggered the statutory 30-month stay of the FDA's decisions on the pending ANDAs. Id. ¶¶ 10, 110–111.[5] The cases against Teva, Actavis, and Anchen were consolidated under the Teva docket. Id. ¶ 113. See Shire LLC v. Teva Pharmaceuticals USA, Inc., 10-cv-00329, ECF No. 15 (Aug. 2, 2010). In March 2012, Shire's co-plaintiffs dedicated the '290 Patent to the public, which effectively surrendered it. Id. ¶ 117. The DPPs claim that the documents that would have rendered the '290 Patent invalid had already been produced in March 2011. Id.

On September 4, 2012, Shire settled with TWi/Anchen. The settlement agreement provided that:

[redacted]

Id. ¶¶ 11, 119.

[4] Anchen later transferred its ANDA to TWi Pharmaceuticals ("TWi") (together with Anchen, "TWi/Anchen"). CAC ¶ 9.

[5] Shire also sued other generic manufacturers in other district courts. CAC ¶ 112. The cases against Impax and Watson and Sandoz settled before any dispositive motions practice. The DPPs allege that the claim construction opinions issued in both cases were damaging to Shire's case. Id.

From September 17 through September 20, 2012, there was a bench trial on Shire's claims against Actavis and Teva. Id. ¶ 120. The DPPs allege that, at the trial, Actavis and Teva presented "compelling evidence" that the '599 and '794 Patents were invalid as either anticipated or obvious in light of prior art. Moreover, they assert that it appeared likely that Actavis would prevail based on investment banking forecasts, the strength of the evidence at trial, and the statements made by Actavis's CEO in early 2013 that time was "of the essence" to settle with Shire in order to obtain highly favorable terms. Id. ¶¶ 121, 140.

On October 5, 2012, the statutory 30-month stay expired on Actavis's ANDA, and it was approved that same day. Id. ¶ 139. As a result of the successful ANDA, the applicable statutes gave Actavis 180 days free from other generic competition once it launched the generic. Id.

On April 25, 2013, before any ruling issued following the bench trial on the Intuniv Patents, Shire and Actavis entered into a Settlement Agreement, which also incorporated by reference a related License Agreement. Id. ¶ 141. The DPPs allege that, as part of the settlement, Actavis agreed to delay the entry of its generic until December 1, 2014, in exchange for Shire's agreement not to launch any AG during Actavis's 180-day exclusivity period (otherwise known as a "no-AG agreement"). Id. ¶¶ 143−144. Specifically, under the License Agreement, Shire reserved the right to launch the AG directly or through an affiliate, but explicitly promised not to market the AG through third parties. Id. ¶ 144. The DPPs contend that, given the economic and regulatory realities, the Defendants were aware at the time of the settlement that Shire would never actually market the AG by itself. Id. Thus, using the false possibility of Shire launching the AG itself or through an affiliate, the License Agreement disguised what was functionally a no-AG agreement. Id. ¶¶ 78, 144−145. In fact, Shire never did launch an AG. Id. ¶ 145.

Because of Shire's earlier settlement with TWi/Anchen, the DPPs allege that Actavis was incentivized to negotiate with Shire to avoid competition from an AG launched by TWi/Anchen. Id. ¶¶ 144−145. Absent the no-AG agreement, TWi/Anchen, at Shire's behest, would have launched an AG, and Actavis would not have agreed to delay generic entry until December 1, 2014. Id. ¶ 148. The DPPs also aver that a reasonable generic manufacturer would have prevailed in the patent litigation against Shire and thus would have successfully launched its generic before December 1, 2014, most likely in May 2013. Id. They further claim that a reasonable generic manufacturer would have assessed its chances of winning the litigation to be so high as to risk launching its generic while the patent litigation was still pending, and thus would have launched as early as October 5, 2012. Id.

In sum, the no-AG agreement between the Defendants purportedly constituted an anticompetitive, illegal "reverse payment" under FTC v. Actavis, 133 S. Ct. 2223 (2013), which resulted in Shire realizing approximately $424 million in additional sales and Actavis generating approximately $84.5 million in profits. CAC ¶¶ 152−154. See FTC v. Actavis, 133 S. Ct. at 2227 (generally describing a "'reverse payment' settlement agreement" as one that "requires the patentee to pay the alleged infringer, rather than the other way around"). To partially offset the large flow of profits to Actavis as a result of the no-AG agreement, the settlement also provided Shire a 25% "royalty" on gross profits earned during the 180-day exclusivity period. Id. ¶ 146. The royalty added an additional incentive for Shire to stay out of the market during Actavis's exclusivity period. Id. The DPPs conservatively estimate that, overall, the size of the reverse payment from Shire to Actavis was nearly $53 million (the difference between Actavis's actual profits and its anticipated profits when competing with an AG), although it could be over $100 million. Id. ¶¶ 157, 160. Absent this agreement, American purchasers of Intuniv would have

purportedly saved approximately half a billion dollars. Id. ¶ 2. The settlement was designed to allow Shire to maintain a monopoly over the Intuniv market until December 1, 2014, in exchange for Actavis's subsequent 180-day exclusivity period free from competition from a Shire AG. As a result, there were two distinct periods of anti-competition: (1) from at least May 2013 through December 1, 2014 when Shire controlled the market, and (2) for 180 days after December 2, 2014 during which Actavis controlled the generic market. Id. ¶ 163. The other generic manufacturers launched their generic Intuniv drugs shortly after Actavis's 180-day exclusivity period ended on June 2, 2015. Id. ¶¶ 165−166.

Although the CAC also includes other allegations, the briefs do not put these allegations at issue, and thus the Court does not discuss them. The CAC asserts the following causes of action: conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1 against all Defendants (Count One), and monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2 (Count Two) against Shire. The DPPs seeks treble damages, costs, and reasonable attorneys' fees.

III. LEGAL STANDARD

On a motion to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept as true all well-pleaded facts, analyze those facts in the light most hospitable to the plaintiff's theory, and draw all reasonable inferences from those facts in favor of the plaintiff. U.S. ex rel. Hutcheson v. Blackstone Med. Inc., 647 F.3d 377, 383 (1st Cir. 2011). In ruling on a motion under Rule 12(b)(6), the Court "must consider the complaint, documents annexed to it, and other materials fairly incorporated within it," which "sometimes includes documents referred to in the complaint but not annexed to it" and "matters

that are susceptible to judicial notice." Rodi v. S. New Eng. Sch. of Law., 389 F.3d 5, 12 (1st Cir. 2004).

Although detailed factual allegations are not required, a complaint must set forth "more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). A "formulaic recitation of the elements of a cause of action" is not enough. Id. To avoid dismissal, a complaint must set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Gagliardi v. Sullivan, 513 F.3d 301, 305 (1st Cir. 2008) (internal quotations and citation omitted).

Further, the facts alleged, when taken together, must be sufficient to "state a claim to relief that is plausible on its face." A.G. ex rel. Maddox v. Elsevier, Inc., 732 F.3d 77, 80 (1st Cir. 2013) (quoting Twombly 550 U.S. at 570). "The plausibility standard invites a two-step pavane." Id. (quoting Grajales v. P.R. Ports Auth., 682 F.3d 40, 45 (1st Cir. 2012)). "At the first step, the court 'must separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited).'" Id. (quoting Morales-Cruz v. Univ. of P.R., 676 F.3d 220, 224 (1st Cir. 2012)). "At the second step, the court must determine whether the remaining factual content allows a 'reasonable inference that the defendant is liable for the misconduct alleged.'" Id. (quoting Morales-Cruz, 676 F.3d at 224). "Although not equivalent to a probability requirement, the plausibility standard asks for more than a sheer possibility that a defendant has acted unlawfully." Boroian v. Mueller, 616 F.3d 60, 65 (1st Cir. 2010) (internal quotations and citation omitted). See also Sepulveda-Villarini v. Dep't of Educ. of P.R., 628 F.3d 25, 29 (1st Cir. 2010) (citing Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)) ("The make-or-break standard . . . is that the combined allegations, taken as true, must state a plausible, not a merely conceivable, case for relief.").

IV. DISCUSSION

The DPPs assert that the settlement agreement between the Defendants contained an implicit no-AG agreement, which constituted an unlawful reverse payment under FTC v. Actavis. Both Shire and Actavis argue that the CAC should be dismissed because it fails to plausibly allege a no-AG agreement. Actavis also argues that a no-AG agreement does not, as a matter of law, constitute an illegal reverse payment under FTC v. Actavis because a no-AG agreement is simply an exclusive license not subject to antitrust scrutiny. [6]

A. Unlawful Reverse Payments Under FTC v. Actavis

The Supreme Court has held that settlements in which a patent holder, who originally brought suit for patent infringement, pays a patent challenger to delay entry of its generic into the market can be actionable under federal antitrust laws. See FTC v. Actavis, 133 S. Ct. at 2227. Such pay-to-delay provisions in settlement agreements are commonly referred to as "reverse payments." Id. In order to determine whether a reverse payment is unlawful, the Supreme Court instructs courts to apply a rule of reason analysis that considers "[the reverse payment's] size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Id. at 2237. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 544−545 (quoting Arizona v. Maricopa Cty. Med. Soc'y, 457 U.S. 332, 343−344 (1982)) ("The 'rule of reason' is a means of evaluating a restraint on trade and determining 'whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition.'"). The rule of

[6] For the most part, the Defendants appear to present substantially similar or consistent arguments. In some instances, they explicitly reference the other's argument and incorporate it by reference. Accordingly, the Court does not generally distinguish between which Defendant made each argument. To the extent it seems clear that the Defendants do not incorporate each other's arguments, the Court attributes it to the Defendant that raised it.

reason analysis is used to determine whether the complained of conduct results in "significant unjustified anticompetitive consequences." FTC v. Actavis, 133 S. Ct. at 2238. "[I]t is the prevention of that risk of competition—eliminating 'the risk of patent invalidation or a finding of noninfringement' by 'paying the challenger to stay out' of the market (for longer than the patent's strength would otherwise allow)—that 'constitutes the relevant anticompetitive harm,' which must then be analyzed under the rule of reason." King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388, 404 (3d Cir. 2015), cert. denied, 137 S. Ct. 446 (2016) (quoting FTC v. Actavis, 133 S. Ct. at 2236–2237). The rule of reason analysis eventually, although not at this stage, requires a plaintiff to prove "that the alleged agreement involved the exercise of power in a relevant economic market, that this exercise had anti-competitive consequences, and that those detriments outweighed efficiencies or other economic benefits." Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I., 373 F.3d 57, 61 (1st Cir. 2004).

The First Circuit subsequently decided that non-cash payments can also constitute actionable reverse payments within the meaning of FTC v. Actavis. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 549. In In re Nexium (Esomeprazole) Antitrust Litig., the First Circuit stated that, under a functional application of FTC v. Actavis, "'no-AG' provisions . . . may constitute a reverse payment subject to antitrust scrutiny." In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 42 (1st Cir. 2016). Even if arguably dictum, as Actavis suggests, this conclusion merits some weight. See Haag v. United States, 736 F.3d 66, 70 (1st Cir. 2013) (quoting Dedham Water Co. v. Cumberland Farms Dairy, Inc., 972 F.2d 453, 459 (1st Cir.

1992)) ("'[C]ourts often, quite properly, give considerable weight to dictum—particularly to dictum that seems considered as opposed to casual.'").[7]

Moreover, other courts have explicitly held that no-AG agreements can constitute illegal reverse payments. See King Drug Co. of Florence, 791 F.3d at 403 ("[W]e think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason."). See also In re Opana ER Antritrust Litig., 162 F. Supp. 3d 704, 717 (N.D. Ill. 2016) (holding that the no-AG agreement could be a reverse payment because "the [no-AG agreement] transferred the profits [brand company] would have made from its AG to [generic company]—plus potentially more, in the form of higher prices, because it enabled [generic company] to have a generic monopoly instead of a generic duopoly"); In re Actos End Payor Antitrust Litig., No. 13-cv-9244, 2015 WL 5610752, at *18 (S.D.N.Y. Sept. 22, 2015), aff'd in part and vacated on other grounds, 848 F.3d 89 (2d Cir. 2017) ("The Court agrees with Plaintiffs that such arrangements [no-AG agreements] trigger antitrust scrutiny due to their potential anticompetitive effect."); In re Aggrenox Antitrust Litig., 94 F. Supp. 3d at 242−243 (holding that no-AG agreement may constitute large and

[7] The First Circuit states in full that "[u]nder this functional approach, 'no-AG' provisions—in which the brand-name manufacturer agrees not to market an 'authorized generic' version of the drug for a certain period of time—and other settlement provisions in which some advantage is transferred from the patent holder to the alleged infringer may constitute a reverse payment subject to antitrust scrutiny." In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34, 42 (1st Cir. 2016). Actavis argues that the statement is not even dictum, and that the issue of whether a no-AG provision can be a reverse payment remains open after Loestrin. In Loestrin, the First Circuit explicitly declined to address whether the plaintiffs had adequately pled that the no-AG provision was an unlawful reverse payment and only addressed whether non-cash payments can be actionable under FTC v. Actavis. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 552−553. The Court agrees that the use of the word "may" in the context of whether a no-AG agreement is ever actionable might appear ambiguous. Nonetheless, the statement in Nexium strongly suggests that the Court should apply a functional analysis to the no-AG agreement at issue to determine whether or not it can be an unlawful reverse payment. Further, as explained infra, the Court does not rely only on this language in Nexium to hold that a no-AG provision may constitute an unlawful reverse payment.

unjustified reverse payment); United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014) ("I agree with the courts who have held that a no-authorized-generic term can constitute a payment."); In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (holding that no-AG provision may constitute unlawful reverse payment); In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("This Court does not see fit to read into the [FTC v. Actavis] opinion a strict limitation of its principles to monetary-based arrangements alone.").

In short, it is well recognized that a generic monopoly during the 180-day exclusivity period is highly lucrative. See FTC v. Actavis, 133 S. Ct. at 2229 (quoting Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1579 (2006)) (noting that first-to-file exclusivity period is "possibly 'worth several hundred million dollars'"). If a brand company markets an AG during this period, it captures part of the generic market, and thereby cuts into the generic company's revenue. When a brand company promises not to market an AG during that time period, it gives up its potential share of the generic market, ceding it to the generic company, which effectively transfers value to the generic company. Further, the First Circuit has already held that reverse payments may take the form of non-cash payments. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 549. Accordingly, an agreement not to market an AG in exchange for a patent challenger abandoning its lawsuit can constitute a meaningful transfer of value from the brand company to the generic company that has unjustified anticompetitive consequences.

Actavis attempts to distinguish King Drug Co. of Florence, 791 F.3d at 393, 397—in which the Third Circuit held that a no-AG agreement may constitute an illegal reverse payment—because the no-AG agreement in King Drug Co. of Florence, unlike here, involved a

provision that precluded the marketing of the AG after the expiration of the patents at issue, and was thus not part of the exclusive patent license. In reaching its decision in FTC v. Actavis, however, the Supreme Court explicitly assumed "that the [settlement] agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent," and nonetheless held that such an agreement could violate the antitrust laws. FTC v. Actavis, 133 S. Ct. at 2230 (emphasis added). See also King Drug Co. of Florence, 791 F.3d at 393 ("The [Supreme] Court rejected the near-irrebuttable presumption, known as the 'scope of the patent' test, that a patentee can make such reverse payments so long as it is paying potential competitors not to challenge its patent within the patent's lifetime."). When there is litigation that challenges both "the patent's validity" and "its actual preclusive scope," "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." FTC v. Actavis, 133 S. Ct. at 2231. Actavis does not attempt to distinguish any of the other cases that hold that a no-AG agreement can be an illegal reverse payment, including those that explicitly reject the very argument that Actavis raises here. See e.g., Teikoku, 74 F. Supp. 3d at 1070–1071 (rejecting argument that a no-AG agreement is not subject to antitrust scrutiny because it is a partially exclusive license); Niaspan, 42 F. Supp. 3d at 751 ("[T]he Court rejects defendants' argument that a no-AG provision has the same economic effect as the grant of an exclusive license to enter the market prior to the expiration of a patent."). Thus, the argument that a no-AG agreement is simply an exclusive license not subject to antitrust scrutiny is unavailing.

Accordingly, the Court holds that a no-AG agreement, even one involving a time period during the pendency of a patent, can constitute an illegal reverse payment within the scope of

FTC v. Actavis. Even if no-AG agreements may constitute actionable reverse payments, however, they are still subject to a rule of reason analysis to determine their legality. See In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 243 (D. Conn. 2015) ("Such a settlement, under [FTC v. Actavis], is not ipso facto unlawful: the parties to the settlement might be able to explain the apparent 'missing' value for the patent-holder in a procompetitive way—and they will have an opportunity to do so under the rule-of-reason framework—in which case the reverse payment may turn out to be justified, or to be entirely illusory.").

B. Whether The DPPs Have Plausibly Alleged An Unlawful Reverse Payment

In order to state a claim at this stage, the DPPs must adequately plead (1) that there was a no-AG agreement and (2) that it was large and unjustified. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 552 (in order to plead a plausible antitrust violation based on a no-AG agreement, "the plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under [FTC v. Actavis].").

Anticompetitive conduct violates the Sherman Act when it stems from "an agreement, tacit or express" and is thus not a product of an "independent decision." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 553 (2007). To allege a plausible antitrust conspiracy, "a complaint must at least allege the general contours of when an agreement was made, supporting those allegations with a context that tends to make said agreement plausible." Evergreen Partnering Grp., Inc. v. Pactiv Corp., 720 F.3d 33, 46 (1st Cir. 2013). Although mere allegations of parallel conduct that is possibly anticompetitive, without any suggestion of an agreement to engage in such conduct, are insufficient under Twombly, the First Circuit has specifically cautioned against heightening the pleading requirements for antitrust cases. The Twombly Court explained that "when allegations of parallel conduct are set out in order to make a [Sherman Act] § 1 claim,

they must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." Twombly, 550 U.S. at 557. However, "allegations contextualizing agreement need not make any unlawful agreement more likely than independent action nor need they rule out the possibility of independent action at the motion to dismiss stage." Evergreen, 720 F.3d at 47.

The DPPs argue that there was an implicit no-AG agreement in the Defendants' settlement that constituted a large and unjustified non-cash payment from Shire to Actavis.[8] The no-AG agreement allegedly enabled Shire and Actavis to charge supracompetitive prices for a longer period than if the patents had been invalidated through litigation or if Actavis had entered the market at risk in October 2012 without a no-AG promise. CAC ¶¶ 148–149. Defendants claim that the settlement was simply composed of legal compromises over entry dates and royalties. In their view, even if a no-AG agreement were actionable, the settlement agreements at issue do not include an explicit no-AG agreement and in fact give Shire the right to market an AG. The DPPs respond that the no-AG agreement was implicit in the terms of the settlement agreements, which themselves were purposefully designed by Defendants to evade antitrust scrutiny.

[8] At the hearing, the DPPs argued that the restriction on third-party distribution of Shire's AG constitutes, on its own, an unlawful reverse payment sufficient to withstand the motion to dismiss. The DPPs did not include such allegations in the CAC or raise the theory in their opposition brief, and there is no other indication that they intended to assert this theory of antitrust liability. To the extent the DPPs intended the CAC to include such allegations, they have failed to allege facts that would allow the Court to infer that the partial no-AG agreement, as opposed to the complete no-AG agreement, was large and unjustified. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 552 ("[T]he plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under [FTC v. Actavis]").

[redacted] The DPPs argue that the agreement nevertheless contained a tacit no-AG provision because the Defendants understood that Shire never would (and never actually did) launch its own AG. Coupled with the explicit provision [redacted], this tacit no-AG agreement constituted an unlawful reverse payment.

The DPPs assert that the explicit right of Shire to self-launch an AG was provided in the settlement agreement largely to avoid antitrust scrutiny, rather than to provide a meaningful opportunity for Shire itself to market an AG. "[G]iven the economic and regulatory realities," Shire's reservation of the right to market its own AG "was known to be a false possibility," functionally rendering the agreement "a routine no-AG deal (with only the thinly veiled pretext intended to be used to avoid antitrust scrutiny)."[9] CAC ¶ 144. In addition to the "economic and

[9] The "economic and regulatory realities" described in the CAC involve the Medicaid drug pricing regulations. The CAC states that Shire was incentivized "to avoid Medicaid [Average Manufacturer Price] and best price recalculations for its branded Intuniv sales that might well be required if Shire launched an authorized generic of Intuniv other than through a bona fide third party." CAC ¶ 145. The CAC notes that to avoid the Medicaid regulations, "common industry practice emerged to launch authorized generics through bona fide third party distributors." Id. ¶ 85. The CAC does not explain why avoiding these recalculations was an incentive, although in their brief and at oral argument, the DPPs stated that the brand drug companies were concerned about the spillover effects from how they treat AG sales under the Medicaid regulations on the pricing of their brand products. See [ECF No. 63 at 14−15] (asserting that when a brand company launches an AG directly, rather than through a third party distributor, it must account for the AG's lower price, which, in turn, diminishes the amount that the brand can be reimbursed

regulatory realities," the DPPs allege the following facts in support of the existence of an unlawful agreement. First, Shire's regular practice, which was also common to the industry, was to launch AGs through third party distributors. Id. ¶¶ 85, 145. Prior to the agreement with Actavis, Shire had in fact planned to launch an Intuniv AG through TWi/Anchen. Id. ¶ 119. See also [ECF No. 63 at 11] ("Shire planned to launch an authorized generic with [TWi/Anchen]."). Second, Shire had no "captive subsidiary" through which it could itself have easily launched an AG. CAC ¶ 145. Third, the royalty payment Actavis agreed to pay Shire both incentivized Shire not to launch an AG and evidences the substantial value Actavis secured through the no-AG agreement (*i.e.*, it was effectively a kickback). Id. ¶¶ 145–146. Fourth, Shire never did launch an Intuniv AG. Id. ¶ 145. Fifth, the Defendants only settled following a trial that Actavis seemed poised to win. Id. ¶¶ 118, 120–138, 141.

These allegations satisfy Twombly because they plausibly suggest that an implicit no-AG agreement existed. See Evergreen, 720 F.3d at 47–51 (holding that plaintiff alleged a plausible conspiracy when it alleged parallel conduct that included proactive destructive conduct, the specifics of the agreement, industry information suggesting collusive practices are more common in concentrated industries, and practices that facilitated the alleged conspiracy). The fact that the settlement documents [redacted]. A documented provision [redacted] does not on its own make the existence of an implicit no-AG agreement implausible. At bottom, whether or not the License Agreement conclusively establishes that there was no implicit no-AG agreement turns on issues of fact that are not appropriately resolved at this stage.

through Medicaid for brand-name prescriptions). See also See July 20, 2017 Hearing Tr. 45:2–22; 49:9–13.

Relying on Twombly, Shire argues that the allegation that Shire never launched an AG cannot support an inference that the decision was the result of an anticompetitive agreement. Twombly held that parallel conduct that is as consistent with a conspiracy as it is with independent action cannot alone satisfy the plausibility requirement, but it does not preclude the Court from considering Shire's failure to market an AG as one factor in analyzing whether a no-AG agreement plausibly existed. The First Circuit in Evergreen made clear that "allegations contextualizing agreement need not make any unlawful agreement more likely than independent action nor need they rule out the possibility of independent action at the motion to dismiss stage." Evergreen, 720 F.3d at 47. Although Shire's failure to launch an AG is not alone sufficient to support the inference, it may still suggest the existence of a conspiracy, at least when coupled with other allegations.

Shire also argues that a royalty payment cannot form the basis of a reverse payment claim. The CAC does not allege that the royalty payment was itself a reverse payment. Instead, it is part of the context that makes the existence of a no-AG agreement plausible. Including a royalty payment in a settlement agreement does not insulate it from antitrust liability where a reverse payment otherwise exists. Further, the fact that a royalty payment may be lawful on its own does not prohibit the Court from considering it as part of the context of the conspiracy where it allegedly created an incentive for Shire not to market its own AG. The Court must "evaluate the cumulative effect of the factual allegations," Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 14 (1st Cir. 2011), and read "the complaint . . . as a whole, not parsed piece by piece to determine whether each allegation, in isolation, is plausible." Id. (quoting Braden v. Wal-Mart

Stores, Inc., 588 F.3d 585, 594 (8th Cir. 2009)). The main thrust of the Defendants' arguments require weighing competing inferences, which the Court cannot do at this stage.[10]

V. CONCLUSION

For the reasons explained above, the Court DENIES the motions to dismiss.

SO ORDERED.

Dated: October 10, 2017

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE

[10] To the extent that Defendants argue that the DPPs' reverse payment claims should be dismissed because the CAC does not allege sufficient facts to quantify the amount of the reverse payments, the argument fails. The CAC provides a plausible estimate of the value of the no-AG agreement to both Shire and Actavis, and further alleges that the payment far exceeded the estimated litigation costs. See, e.g., CAC ¶¶ 153–61. This is sufficient at this stage. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 552 (1st Cir. 2016) (holding that Twombly does not require plaintiffs to "provide precise figures and calculations at the pleadings stage" but only that "plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis"); In re Lipitor Antitrust Litig., 868 F.3d 231, 253 (3d Cir. 2017) (holding that plaintiffs adequately pleaded large and unjustified reverse payment where they alleged that the payment was worth hundreds of millions of dollars and far exceeded anticipated litigation costs).